REMARKS

In the last Office Action mailed January 20, 2010, claims 26, 27, 30, 31, 33, 34 and 36-47 were rejected under 35 U.S.C. 101 and 103(a). Reconsideration is respectfully requested for the reasons set forth below.

The 35 U.S.C. 101 Rejections

All pending claims have been rejected under 35 U.S.C. 101, in view of the Federal Circuit's opinion in *In re Bilski*, as reciting a process which is not "tied to a particular machine or apparatus" or does not "transform a particular article to a different state or thing". Reconsideration and withdrawal of this rejection is respectfully requested in view of Supreme Court's recent decision in *Bilski et al v. Kappos*. The Court made it clear that the processes which do not satisfy the "machine-or-transformation test" may be patentable as long as the claims are not directed merely to "laws of nature, physical phenomena, or abstract ideas." None of the pending claims are directed merely to "laws of nature, physical phenomena or abstract ideas" but rather recite specific method or process steps necessary to properly maintain a cardiac emergency readiness program including at least one automated external defibrillator (referred to below as an "AED").

It is also respectfully submitted that all pending claims also satisfy the "machine-or-transformation test." In this regard, independent Claim 26 recites making changes in and to AED equipment located at a facility. More specifically, Claim 26 specifically recites "...causing...modifications in the program to be made including the number and location of" defibrillators as well as "the battery and electrodes for" defibrillators or AEDs. These steps therefore recite the transformation of AEDs both in number as well as replacement of consumable parts. In addition, these steps, along with each and every other step, recite at least one AED and are therefore tied to a particular machine. It is respectfully submitted that the "machine" prong of the "machine-or-transformation test" does not require that the method steps be performed on a "computer processor, etc." as contended by the Examiner. The Supreme Court in *Bilski et al v. Kappos* imposes no such requirement but merely calls for the process to

be "tied to a particular machine" which the pending claims clearly are. In fact, the opinion of Justice Kennedy (Slip Opinion at 8) and the concurring opinion of Justice Stevens (Slip Opinion at 9) agree that "machine-or-transformation" test has its historical roots in and was well-suited for use in the "Industrial Age" (Slip Opinion at 9), but disagree as to whether or not this test is well-suited to testing business method inventions of the "Information Age." To the extent that the Examiner maintains that a process must be performed on a "computer processor" or other Information Age equipment in order to be "tied to a machine," Applicant respectfully submits that the Examiner has ignored the historical development of the "machine-or-transformation" test during the Industrial Age and continuing to maintain this position would be at odds with the clear intent of the Supreme Court as expressed in *Bilski et al. v. Kappos*.

The 35 U.S.C. 103 Rejection of Independent Claim 26

Independent claim 26 has been rejected as obvious over Altman in combination with Becker and the PAED reference. Even assuming for the sake of argument that such a combination could withstand a rigorous *KSR* analysis as required by *Trimed, Inc.v. Stryker Corporation*, ____F.3d____ , 2010 U.S. App. LEXIS 11700 (Fed. Cir. 2010) (and no such analysis has been offered by the Examiner, as discussed below), the combination of these three references is still not concerned with auditing or certifying an existing cardiac emergency readiness programs having at least one previously deployed AED, as set forth below.

The rejection of independent Claim 26 relies upon Altman as disclosing the "auditing" of such a cardiac emergency readiness program but, Applicant finds no disclosure by Altman of any "auditing" whatsoever. Altman does disclose certain considerations in the initial implementation of an AED program, i.e., "[h]ow are AED programs implemented" including "first steps" (emphasis added). There is however, as far as Applicant can tell, no disclosure by Altman of "auditing" an AED program once the program has been implemented.

In this regard, the rejection concludes that Altman's mention of "Universal Access to Defibrillation" statutes "requiring completion or equivalent training program, including additional refresher courses required to renew certification" constitutes an "audit." Applicant

disagrees. Applicant finds no indication in Altman that the statutes being discussed require an audit of an AED program once it has been implemented. In fact, Applicant finds no discussion in Altman of any public or private oversight of an existing AED program let alone an audit. While Altman clearly mentions that refresher courses may be required for a trainee to retain the trainee's certification, there appears to be no disclosure of any sort of audit to determine if a trainee is due for or completed such a refresher course in order to retain the trainee's certification as required for a facility's certification. Moreover, a trainee's certification is not the same as a facility's certification within the meaning of Claim 26, which will be discussed below in detail.

The rejection of independent Claim 26 also concludes that the determination of "how many devices a company needs, which inherently includes determining proper placement and how many people are being trained" constitutes the disclosure of an "auditing" within the meaning of the claims. However, this conclusion disregards the fact that the "auditing" as recited in the claims involves the "auditing" of an existing AED program, whereas Altman appears only concerned with the initial implementation of AED program, i.e., "first steps," as discussed above. Moreover, Applicant disagrees with the rejection's conclusion that determining "how many devices a company needs" also "inherently includes determining proper placement" of the AED devices. Applicant finds no disclosure in Altman indicating that the "proper placement" or "required locations" for AED's in a facility as recited in claim 26 should provide a "predetermined proximity of the defibrillators to a victim regardless of the location of the victim within the facility." In fact, Altman appears to be silent as to whether a "company's needs" ever require more than one AED at each of the facilities owned or operated by a company regardless of a particular facility's size.

In what appears to be effort to bolster an inherency argument regarding placement of AEDs based on Altman, the rejection of independent Claim 26 first acknowledges that there is no explicit disclosure regarding the placement of AED's in Altman "so as to assure accessibility by providing predetermined proximity of the defibrillators to a victim regardless of the location of the victim with the facility." The rejection then cites Becker as disclosing "a plan for placement of defibrillators in higher-incidence locations." The placement of AEDs at higher-

incidence locations such as each "cluster" of gates at Seattle –Tacoma Airport does not provide "a predetermined proximity" to a victim not in a gate "cluster" area. But perhaps more importantly, Applicant finds no disclosure in Becker of any sort of "audit" of an AED program to determine compliance with a set of specific "minimum requirements" as set forth in the Claim 26. In this regard, Becker expressly states that "[o]ur data do not address the issues of cost-effectiveness, training requirements, maintenance of AEDs, or likelihood that the devices would actually be used when needed." Rather, Becker appears concerned with the effectiveness of AED's at high SCA incidence locations and only concludes that "certain location categories would benefit from public placement of AEDs." (emphasis added).

Altman also does not appear to disclose an "audit" including "a review of the number of personnel at the facility to determine the number and status of trained and certified personnel to use the at least one deployed defibrillator" as recited in independent Claim 26. Notwithstanding the conclusion of the rejection, Altman as discussed above does not appear to be concerned with "auditing" an existing AED program at a facility but only the initial implementation of an AED program at the facility including "the first steps," i.e., the facilities discussed in Altman do not have a least one earlier deployed AED. Altman does not disclose an "auditing" of the "number and status of personnel trained and certified to use" an already deployed defibrillator or AED since no such previously deployed AED exists.

The rejection of independent Claim 26 acknowledges that Altman fails to disclose an audit including "an operational review of the at least one deployed defibrillator including the battery and electrodes of the at least one deployed defibrillator." In an apparent effort to fill this gap, the rejection turns to the PAED reference which broadly discloses "medical control and quality assurance" including "periodic retraining and assessment of the service and AED operators." However, the PAED reference appears silent as to the performance of any operational review of AEDs let alone as part of an auditing of an existing AED program. While there is no doubt that replacement of batteries and electrodes is a requirement of AEDs and such a requirement was well known as of the publication dates of Altman and the PAED reference, there is no indication in Altman or the PAED reference that such timely replacement was the

subject of an audit as recited in Claim 26 as opposed to being left to the AED operators to do or not do as they see fit.

The rejection of independent Claim 26 also concludes that Altman discloses the step of "reporting results of the auditing to the facility so as to cause any necessary modifications to the program ...including the at least one deployed defibrillator." Applicant disagrees. There appears to be no "auditing" of any program including "at least one deployed defibrillator" disclosed by Altman. Rather, Altman appears concerned with the "first steps" of an initial implementation, i.e., "develop and implement AED program, including providing curriculum" as conceded by the rejection and not the auditing of an earlier implemented AED program. It would therefore appear improbable for Altman to provide a "reporting of the results" of an audit on an earlier implemented AED program let alone "cause any necessary modifications" to be made in such an earlier implemented AED program as also recited by independent Claim 26.

Finally, the rejection of independent Claim 26 states that Altman discloses the step of "certifying that the minimum programs requirements for defibrillators including the at least one deployed defibrillator and their usage at the facility have been satisfied." Applicant disagrees. In this regard, the rejection appears to rely on provisions of "Universal Access to Defibrillator" statutes as briefly described by Altman including the requirement for "completion or equivalent training program" which results in the "certification" of a CPR/AED trained responder. First, the certification of a CPR/AED trained responder after completing a CPR/AED training course is something entirely different from the certification of a facility as having met various minimum requirements including the proper number of "certified" trained responders for a particular facility. Second, to Applicant's knowledge, there was no statute in any state at the time of the Altman publication, which dictates the number certified AED/CPR trained responders or AEDs which a facility should have. Third, even if the existence of such a statute were assumed for the sake of argument, there appears to be no disclosure in Altman that anyone certifies compliance with such a statute. As noted above, the word "certify" or "certifying" is only used by Altman in connection with the certification received by a trained responder after completing a CPR/AED course.

The references used in rejecting independent Claim 26 under 35 U.S.C. 103 have been combined without providing any analysis as to why such a combination would be obvious. The rejection simply states that the "claimed invention is merely a combination of old elements, and in the combination each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of combination were predictable." Of course, not one of the elements recited in independent Claim 26 is old for the reasons discussed above. But even if, for the sake of argument, the elements were assumed to be old, the superficial explanation of obviousness falls far short of the *KSR* analysis required in view of the Federal Circuit's recent decision in. *Trimed*, *supra.*:

> "Answering this question usually entails considering the 'interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent in issue." (Citing *KSR,* 550 U.S. at 418).

Trimed, 2010 U.S. App. LEXIS 11700 at *15-16. *See* also *In re Vaidyanathan,* ____F.3d____,____, 2010 U.S. App. LEXIS 10189 (Fed. Cir. 2010) ("*KSR* did not free the PTO's examination process from explaining its reasoning. In making an obviousness rejection, the examiner should not rely on conclusory statements that a particular feature of the invention would have been obvious or was well known. Instead, the examiner should elaborate, discussing the evidence or reasoning that leads the examiner to such a conclusion."). The rejection provides none of the required reasoning and elaboration required by the Federal Circuit as recently articulated by the Court.

For all of the foregoing reasons, reconsideration and withdrawal of the 35 U.S.C. 103(a) rejection of independent Claim 26 is respectfully requested.

The 35 U.S.C. 103 Rejections of the Dependent Claims

Reconsideration and withdrawal of the 35 U.S.C. 103 rejection of the dependent claims is respectfully requested in view of their dependency from independent Claim 26 in addition to the following reasons.

With respect to Claim 27, reconsideration and withdrawal of the rejection is also requested since the claim expressly recites "promoting the facility as having a certified emergency readiness program" (emphasis added). Altman does not appear to disclose an emergency readiness program which is "certified" as discussed above. Altman cannot therefore disclose the promotion of a "certified emergency readiness program" as recited in Claim 27.

With respect to Claim 30, reconsideration and withdrawal the rejection is also requested for the following reason. The rejection erroneously assumes that the language of Altman states that the AED "automatically re-analyzes the victim's condition once the shock is delivered" is an AED "usage review" as recited in this claim. Applicant respectfully submits that the Examiner misunderstands how an AED functions. The automatic re-analysis referred to in Altman is not a usage review but rather an automated feature of an AED that permits the AED to determine on its own whether the victim needs another shock to defibrillate the victim. As Altman notes in commenting on this automated feature, "AEDs will not deliver a shock unless the victim's condition requires it."

With respect to Claim 31, reconsideration and withdrawal of the rejection is requested for the following reason. The Office Action expressly acknowledges that Altman "does not explicitly disclose ensuring compliance with legal requirements associated with the certified cardiac emergency readiness program." The rejection then goes on to reference "liability concerning AED use" at the top of page 3. Altman appears silent as "ensuring compliance with legal requirements associated with any sort of AED program whether certified or not. The reference to Good Samaritan Laws at the top of page 3 simply points out that such laws exist and provides no guidance or assistance as to what steps a party might take advantage of the civil immunity provided by such laws let alone doing so by adopting a certified emergency readiness program.

With respect to Claim 33, Altman does not appear to mention "insurance" or for that matter "liability coverage" but simply discusses legal issues relating to the minimal exposure to liability, for a number reasons, including the Good Samaritan laws. There is no "coordinating insurance coverage" but rather the suggestion that no coordination let alone insurance would be needed since the user of an AED is afforded civil immunity under the Good Samaritan laws.

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